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## MAILED

AUG 12 2009

**OFFICE OF PETITIONS** 

In re Patent No. 7,478,460

: DECISION ON

Issue Date: 01/20/2009

: APPLICATION FOR : PATENT TERM ADJUSTMENT

Application No. 10/785133

: UNDER 37 CFR 1.705(d)

Filed: 02/24/2004 Attorney Docket No.

05918-0324001 / VGCP- No. 7020

This is a decision on the "APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 CFR §1.705(d)," filed March 10, 2009, requesting that the patent term adjustment determination for the above-identified patent be changed from 366 days to 524 days.

The request for reconsideration patent term adjustment is **DISMISSED**.

On January 20, 2009, the above-identified application matured into U.S. Patent No. 7,478,460 with a patent term adjustment of 366 days. This application for patent term adjustment was timely filed within two months of the issue date of the patent. See 37 CFR 1.705(d).

Patentees request recalculation of the patent term adjustment based on the decision in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant to Wyeth, a PTO delay under §154(b)(1)(A) overlaps with a delay under §154(b)(1)(B) only if the delays "occur on the same day." Patentees maintain that the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR § 1.703(b), of 409 days and the period of adjustment due to examination delay, pursuant to 37 CFR §1.702(a), of 294 days overlap for a period of 137 days only.

The 409-day period is calculated based on the application having been filed under 35 U.S.C. 111(a) on February 24, 2004, and a request for continued examination (RCE) having been filed in this application on April 8, 2008, three years and 409 days later. Patentees assert that in addition to this 409-day period, they are entitled to a period of adjustment due to examination delay pursuant to 37 CFR 1.702(a) totalling 294 days. This 294-day period is the result of a period of delay of 149 days for the failure by the Office to mail at least one of a notification under 35 U.S.C. 132 not later than fourteen months after the date on which application was filed under 35 U.S.C. 111(a), pursuant to 37 CFR 1.702(a)(1), and a period of delay of 145 days for the failure by the Office to respond to a reply under 35 U.S.C. 132 not later than four months

after the date on which the reply was filed. Patentees provide that the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR § 1.703(b), of 409 days and the period of adjustment due to examination delay, pursuant to 37 CFR §1.702(a), of 294 days overlap for a period of 137 days only; the period of overlap deemed by patentee to run from February 25, 2007, to July 11, 2007.

Under 37 CFR 1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR 1.702 reduced by the period of time equal to the period of time during which patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704. In other words, patentees are entitled to the period of Office delay reduced by the period of applicant delay.

Patentees do not dispute that the total period of Office delay is the sum of the period of Three Years Delay (409 days) and the period of Examination Delay (294 days) to the extent that these periods of delay are not overlapping. Patentees contend that the Three Year Delay period overlaps with the period of examination delay by 137 days only. Accordingly, patentees submit that the total period of adjustment for Office delay is 566 days, which is the sum of the period of Three Year Delay (409 days) and the period of Examination Delay (294 days), reduced by the period of overlap (137 days). As such, patentees assert entitlement to a patent term adjustment of 524<sup>1</sup> days (409 days + 294 days reduced by 137 days overlap – 43 days (applicant delay)).

The Office agrees that as of the filing of the RCE on April 8, 2008, the application was pending three years and 409 days after its filing date. The Office agrees that certain action was not taken within the specified time frame, and thus, the entry of a period of adjustment of 294 days is correct. At issue is whether patentees should accrue 409 days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as 294 days for Office failure to take a certain action within a specified time frame (or examination delay), less overlap as calculated by Patentees.

The Office contends, however, that the 294 days of examination delay overlap with 409 days of delay in issuance of the patent. Patentees' calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

To the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 35 CFR 1.703(f) provides that:

<sup>&</sup>lt;sup>1</sup> Patentee's incorrectly conclude that 566 days reduced by 43 days is 524 days, as opposed to 523 days.

To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of Patentees. The rule was slightly revised to more closely track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in

corresponding § 1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3-year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718<sup>2</sup>

As such, the period for over three-year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application was filed overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the filing date of the application.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the entire period during which the application was pending before the Office, February 24, 2004, as terminated by the filing of the RCE on April 8, 2008. Prior to the issuance of the patent, 294 days of patent term adjustment were accorded for the Office failing to respond within a specified time frame during the pendency of the application. All of the 294 days for Office examination delay overlap with the 409 days of Office delay in issuing the patent. During that time, the issuance of the patent was delayed by 409 days, not 409 days + 294 days. The Office took 14 months and 149 days to issue a first Office action, and four months and 145 days to respond to a reply under 35 U.S.C. 132. Otherwise, the Office took all actions set forth in 37 CFR 1.702(a) within the prescribed timeframes. Nonetheless, given the initial 294 days of Office delay, and the time allowed within the time frames for processing and examination, as of the filing date of the RCE, the application was pending three years and 409 days. Accordingly, 409 days of patent term adjustment was properly entered because the 294 days attributable to grounds specified in § 1.702(a) overlaps with the period of delay of 409 days attributable to the delay in the issuance of the patent.

<sup>&</sup>lt;sup>2</sup> The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106<sup>th</sup> Cong. 1<sup>st</sup> Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999)(daily ed. Nov. 17, 1999).

Accordingly, at issuance, the Office properly accorded an overall adjustment of 366 days (409 days of Office delay less 43 days of applicant delay).

In view thereof, no adjustment to the patent term will be made.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Telephone inquiries specific to this matter should be directed to Attorney Derek Woods, at (571) 272-3232.

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**Petitions Attorney** 

Office of Petitions

Office of the Deputy Commissioner

for Patent Examination Policy